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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,108	01/25/2002	Geert Plactinck	D00590.70011.US	1549

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

<b>Application No.</b> 10/057,108	<b>Applicant(s)</b> PLAETINCK ET AL.	
<b>Examiner</b> Joseph T. Woitach	<b>Art Unit</b> 1632	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 28 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.0(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-41.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/03 or PTO-1449) Paper No(s). \_\_\_\_\_  
13. ☒ Other: See Continuation Sheet.

*Joe Woitach*  
AU1632

Continuation of 5. Applicant's reply has overcome the following rejection(s):

Regarding the claim for priority, while it was not previously noted in the instant application, related application 09/347,311 has been reviewed for the presence of the certified copies of the priority documents of the foregoing priority documents. A copy of both documents are present. Further, in light of the evidence in the declaration and preliminary amendments claiming priority of the parent application in which these documents are found, Applicants arguments that the claim for priority is correct and does not require a petition is found convincing.

In light of the new priority date accorded the instant application, the rejection made under 35 USC 102(a) over Timmons et al. has been obviated. The new priority date July 3, 1998, antedates the publishing date of Timmons et al. October 1998.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicants argue that Fire et al. US Patent 6,506,559 should not qualify as a 102(e) type reference because embodiments of the instant claims are not taught in the provisional application, thus would not be considered prior art. Applicants point to specific embodiments of claims 1, 3 and 38 arguing that they are not taught in provisional application 60/068,562 on which '559 claims benefit. In addition, it is noted that overcoming the art rejection obviates the provisional obvious double patenting. See Applicants Amendment, pages 8-9 Applicants arguments have been fully considered, but not found persuasive.

A review of 60/068,562 indicates that there is support for all the limitations of the instant claims. First, with respect to providing a construct that has a promoter operable linked to the dsDNA to be expressed, '562 clearly teaches that the dsDNA can be made in vivo, and provides various means including the use of viral vectors for expression in vivo. For transcription in vivo, '562 specifically teaches to use a 'regulatory region' which includes the use of a promoter (page 7, lines 10-15). It is noted that there is no specific recitation for a transcription factor binding to the promoter taught in '562, however this is how a promoter operatively functions in vivo. With respect to looking at a phenotype, the specification of '562 is replete with teaching that affecting the gene can result in affecting a characteristic of the resulting organism. Moreover, it is proposed that the methodology be used to analyze gene function to generate models relevant to that gene (see for example bottom of page 1, figure 1 discussing affect on phenotype and general discussion for the affect on unc-22 in twitching phenotype. Finally, with regard to the generation of a cDNA library or genomic library, again it is noted that delivery taught by '562 includes the specific teaching for the use of 'transgene as well as viral vectors to express a sequence in a cell of interest (for example page 6, lines 6-16). It is noted that there is no specific recitation that a cDNA or genomic library is made, but clearly '562 teaches to make several constructs for several genes based on the mRNA and gene sequences of the gene of interest (see figure 1 for example). It appears that Applicants are taking a narrow view on what is encompassed by a 'library'. In this case, the breadth of the claim is being interpreted to be providing one or more sequences, which '562 teaches. In the art, it is also recognized that a library of every mRNA and gene sequence could be made and incorporated into a library, however this interpretation would not work in the context of the claimed invention because having a copy of every gene sequence and preventing every gene from being expressed will not provide an observable selective affect on a phenotype. Clearly providing every sequence to a cell and affecting every gene would result a nonfunctional cell and probably be lethal to an organism as an in vivo model. Applicants arguments have been fully considered, but not found persuasive because each of the limitations of the instant discussed by Applicants is taught in the '562 application.

Continuation of 13. Other: The first action on the merits, mailed 6/3/2004, and the final office action, mailed 12/23/2004, for the instant application are attached. Each are provided for Applicants' records and to demonstrate the 35 USC 102 made using Fire et al. was not a new rejection. Accordingly, Applicants arguments that the finality of the prosecution be considered is not found persuasive because Fire et al. has been of record as of the first action. See also Examiners IDS filed with the first action citing Fire et al. reference.